

APPLICATION FOR UNITED STATES LETTERS PATENT

for

RESPONSIVE MANUFACTURING AND INVENTORY CONTROL

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## CUSTOM MANUFACTURING OF IMPLANTABLE MEDICAL DEVICES

This application claims priority to Provisional Patent Application 60/180,289 filed February 4, 2000, and incorporates the specification and drawings in their entireties by reference herein.

### FIELD OF THE INVENTION

The present invention relates to systems and methods of manufacturing medical devices. Specifically, the invention relates to an interactive system in which a manufacturing computer server interacts with various data centers or hubs to collect enabling information for specific build-to-order devices customized to the customer's requirements. The system is interactive with an information management system that is integrally and seamlessly connected with patients, hospitals, sales offices, and related information hubs. More specifically, the manufacturing and inventory control system of the present invention provides an automated and interactive system which derives manufacturing requirements, on a real-time basis, for replacing medical devices and components which have recently been consumed or implanted based on inputs from the various information hubs connected to a web-enabled information communication system.

### BACKGROUND OF THE INVENTION

Over the years, many implantable devices have been developed to monitor medical conditions and deliver therapy to a patient. Such devices included electrical stimulation devices for stimulating body organs and tissue to evoke a response for enhancing a body function or to control pain, and drug delivery devices for releasing a drug bolus at a selected site. Other more passive implantable and wearable medical devices have been developed for monitoring a patient's condition.

Chronically implanted cardiovascular devices for monitoring cardiovascular conditions and providing therapies for treating cardiac arrhythmias have vastly improved patients' quality of life as well as reduced mortality in patients susceptible to sudden death due to intractable, life threatening tachyarrhythmias.

Such implanted devices can also process the patient's electrogram and any measured physiological conditions employed in the diagnosis and store the data, for subsequent telemetry out upon interrogation by the external programmer. In general,

the manner of communicating between the transceivers of the external programmer and the implanted device during programming and interrogating is referred to as telemetry.

5 The short range of conventional device telemetry is itself viewed as unduly limiting the communication of information over a long distance. In the medical monitoring field, longer range, continuously accessible telemetry has been sought and systems for doing so have been proposed. In U.S. Pat. No. 5,113,869 *Implantable Ambulatory Electrocardiogram Monitor* to Nappholz, et al, for example, an implanted ambulatory ECG patient monitor is described that is provided with longer range  
10 telemetry communication with a variety of external accessory devices to telemeter out alarm signals and ECG data and to receive programming signals. The high frequency RF signals are encoded, including the implanted device serial number, to ensure that the communication is realized only with the proper implanted device and that it is not misprogrammed.

15 A remote, external programmer and analyzer as well as a remote telephonic communicator are also described that may be used in addition to, or alternately to, the personal communicator alarm and/or the full disclosure recorder. The programmer and analyzer may operate at a distance to the implanted AECG monitor to perform programming and interrogation functions. The implanted AECG may automatically  
20 transmit a beacon signal to the programmer and analyzer to initiate an interrogation function to transmit data to the programmer and analyzer on detection of an arrhythmia or a malfunction of the implanted AECG monitor detected in a self-diagnostic test. Or by setting a timer in the personal communicator alarm, the implanted AECG monitor may be automatically interrogated at preset times of day to  
25 telemeter out accumulated data to the telephonic communicator or the full disclosure recorder. The remote telephonic communicator may be part of the external programmer and analyzer and is automatically triggered by the alarm or data transmission from the implanted AECG monitor to establish a telephonic communication link and transmit the accumulated data or alarm and associated data to  
30 a previously designated clinic or physician's office through a modem.

A similar hand-held interrogator for an implanted pacemaker-cardioverter-defibrillator device is disclosed in U.S. Pat. No. 5,336,245, *Storage Interrogation Apparatus for Cardiac Data*, issued to Adams and Kroll in 1994, wherein the data accumulated in the limited capacity memory implanted device is telemetered out to a larger capacity, external data recorder. The accumulated data is also forwarded to a clinic employing an auto-dialer and FAX modem resident in a personal computer-based, programmer/interrogator.

U.S Patent No. 5,752,976, *World wide patient location and data telemetry system for implantable medical devices*, issued to Duffin, et al, in May 1998, referenced herein in its totality, is instructive for the present invention. This patent describes a system for communicating patient device information to and from a medical device implanted in an ambulatory patient and with a remote medical support network comprising: an implanted device telemetry transceiver within the implanted medical device for communicating data and operating instructions to and from the medical device in a coded communication. The implanted device telemetry transceiver has a transceiving range extending outside the patient's body a predetermined distance sufficient to receive and transmit coded telemetry communications at a distance from the patient's body. An external patient communications control device is adapted to be located in relation to the patient within the device transceiving range. The patent also describes a system controller for facilitating communications, an implant wireless interface including a control device telemetry transceiver for receiving and transmitting coded communications between the system controller and the implant device telemetry transceiver, a global positioning system coupled to said system controller for providing positioning data identifying the global position of the patient to the system controller. Also described is a means for communicating with the remote medical support network, a communications network interface coupled to the system controller and a communications method for selectively enabling the transmitting of the positioning data to the medical support network and for selectively receiving commands from the medical support network. The medical support staff may initiate data/programming communications with the implanted medical device.

U.S. Patents No. 5,891,180, Interrogation of an Implantable Medical Device Using Audible Sound Communication, to Greeninger et al, and No. 6,082,367, Audible Sound Communication from an Implantable Medical Device, to Greeninger and Thompson, both hereby incorporated by reference, are instructive on how data  
5 may be interrogated and telemetered out of the implanted device.

One of the issues unresolved by the '976 patent is the question of how to use this system to ensure that the implanting institution has an adequate inventory of implanted devices that may or may not be customized to the requirements of the said institution. If the information about inventory status at the implanting institution,  
10 such as the implantation of a medical device (a reduction in inventory) could be telemetered to the manufacturing site, the manufacturer could then build an identical device to replace the recently implanted device—a process called “build-to-order”.

Build-to-order manufacturing and control systems are well known to those familiar with the art. Such systems were pioneered by Dell USA, when the  
15 company's founder, as far back as 1985, began to manufacture and assemble computers to meet the needs of the user customer. This method of manufacturing and delivery of the product has been further enhanced by allowing potential customers to specify the exact type of desktop or laptop computer s/he wishes to purchase. Indeed, the customer may now specify exactly those specific requirements s/he requires, as  
20 ordered under a protocol called Dell4Me™. For example, a standard computer might come equipped with a standard CD-ROM drive. An individual customer may, however, wish to have a CD-RW (Read/Write) capability. By specifying this requirement in an order, the Dell Manufacturing site builds the computer with this and other customized requirements as specified by the customer. Overhead, in the form of  
25 an outlet store with its accompanying sales personnel and incremental costs, are non-existent. As a result, Dell USA is able to consistently provide quality products at consistently lower costs, as compared to its competition. Dell USA holds well over 200 patents, many of which relate directly to the design and implementation of its build-to-order process. To mention but two such patents, we may cite U.S. Patent  
30 Nos. 5,894,571 *Process for Configuring Software in a Build-to-Order Computer*

*System*, issued to O'Connor, and 5,995,757 *Software Installation and Testing for a Build-to-Order Computer System*, both hereby referenced in their totality.

Another model that may be cited comes from IBM that holds U.S. Patent No. 6,078,900 in June, 2000, *Method for Estimating Stock Levels in Production-Distribution Networks with Inventory Control*, issued to Amberg et al., also referenced herein in its totality. That invention provides computer software for business management and a computer implemented method for estimating stock levels in production/distribution networks with inventory control.

There are many similarities between the computer industry and the medical device industry. Thus, it should be possible to adapt and improve upon these well-known build-to-order systems and methods to fit the specific and customized requirements of the implanting physicians at individual medical institutions

Medical device industries are growing at a rapid rate with a corresponding rapid growth and change in their production processes. At present, the distribution of these products requires multiple stockholding points. One of the great challenges in the medical device environment is a company's ability to meet end-customer demand for an adequate inventory to provide immediate availability for medical devices for which the need cannot be predicted in advance. Further, the need to implant products before obsolescence and managing a smooth transition into new products pose various strategic and manufacturing challenges. Furthermore, consuming (implanting) devices prior to the expiration of a device's shelf life and managing the transition to newly approved devices (e.g., by the FDA) pose additional challenges.

If inventories are managed successfully, rewards can be tremendous. However, the penalty for keeping too little stock or failure to replace stock in a hospital goes beyond the cost of foregone revenue for both the manufacturer and the hospital. It includes the potential for loss of life because the individual required medical device is not available. The penalty for keeping too much stock in inventory, on the other hand, includes the cost of financing a large inventory thereby reducing profit margins to those medical institutions. Consuming (implanting) devices prior to the expiration of a device's shelf life and managing the transition to newly approved devices (e.g., by the FDA) pose additional challenges.

The initial stocking of inventory, as currently practiced, involves the manufacturer's representative, and a person at the institution who is intimately familiar with the usage of medical devices and the number of devices used by the medical institution, often the hospital administrator. Assuming the institution has purchased a certain number of devices, the representative ensures that the institution has a certain number of these devices on the "shelves." The type of device and their number will reflect the nature and content of the contract signed between the institution and the manufacturer and is usually based on expected, rather than actual, usage. Thus, there may be a distribution between basic, advanced, and more advanced technology, again conforming to the nature of the contract that governs the sale of such devices. In general and as currently practiced, the inventoried devices are all standard devices, that is, devices that meet overall general requirements of the worldwide physician community.

The manufacturer's representative maintains that initial inventory. If, however, and for one reason or another, the physician implanter has a greater number of patients who require the implantation of a medical device of one sort or another, the inventory of specific medical devices may become depleted. The situation often arises where the depletion of devices is not noticed until the physician requests a device to match the needs of the patient to be implanted the next day, or later in the day on which the request is made. What is to be done then? Usually a call is made to the manufacturer's local business office that may or may not have the exact model on hand. If so, someone has to bring it to the institution. This may involve many miles depending on the location of the business office relative to the medical institution. If this device is not available at the local business office, a call will be made to the manufacturer's central office or to the manufacturing facility. In such cases and even when Herculean efforts take place, the device will not usually arrive at the institution in time for the originally scheduled implant. Often the implant must be postponed for several days. This is the primary issue that the present invention addresses.

A secondary issue that must be addressed occurs during those times when the device manufacturer is introducing a new product. The manufacturing facility must have on hand a rather large number of newer devices which the physicians and

institutions will request for use upon approval for implant is received from an approving agency such as the FDA and other such agencies in Europe and Japan. Yet, until approval is given, none of the newer devices may be implanted. Only those that were previously approved may be implanted. If the approval is delayed for one reason or another, the manufacturer must maintain two inventories, one of the older and one of the newer product lines. In such cases, when approval is finally granted and because the physicians usually wish to make use of the newer technology, the manufacturer must usually retrieve the older product inventory and dispose of it in some way or other, usually at an economic loss to the manufacturer which, in turn, can bring about a subsequent increase in cost to the government, insurance payer, or patient.

A further deficiency of the present system is an almost complete inability to manufacture an implantable device that is customized to the requirements of the implanting institution or, even further, to the implanting physician.

The key challenge that the medical device industry must face is to determine where and in what quantities to hold safety stock in the network so as to protect against uncertainties, and to ensure that target customer service levels are met. Aggressive service requires significant inventory planning. Today, the determination of inventory levels is localized and often ad hoc, and not based on an analysis of optimal levels and deployment. As a result, the business impact, in terms of the trade-off between inventory investment and customer serviceability or delinquency, is far from optimal.

Determining the optimal inventory levels in individual medical institutions is extremely difficult, and few real-world inventory management systems have the capability to accurately predict target stock levels. The difficulty of the problem arises from the fact that the quantity of safety stock held at one stocking location, and the policy determining replenishment of inventory at that location, will affect other stockholding locations in the network. A system is needed that accurately represents the interdependencies of all links in a production-distribution network, and allows the manufacturer of medical devices to fill the institution's inventory on an automatic



basis whenever that inventory is depleted by even one device as it is used, even when or if the institution requires specific customized devices.

Modern medical devices contain highly sophisticated hardware and software components that require specialized manufacturing processes. Further, these same devices require replacement on the shelves of a hospital on a timely basis when a unit in inventory is implanted in a patient. Hospitals, physicians, and other patient-care systems operate in a highly constrained economic environment. Inventory control is one way to reduce costs within these medical systems. Thus, a medical device manufacturing system that is interactive with and responsive to this environment is highly desirable. This is especially true if such a system can minimize the need for maintaining a large inventory of these medical devices, while sustaining the institution's ability to deliver efficient and effective medical care.

What is needed is a system that has the following goals: build customized products to refill the medical institution's inventory order, automatic replenishment of stock in days, and the tracking of manufacturing and product information in order to effectively service customers.

#### SUMMARY OF THE INVENTION

This invention builds on the previously filed application 09/430,208, *Automatic Invoice Upon Pacemaker Implant* by Linberg on Oct. 29, 1999, hereby referenced in its totality, which describes an auto-invoicing system and a co-pending application, *Responsive Manufacturing and Inventory Control*, that describes a system for manufacturing and delivery of standard medical devices to medical institutions on a timely basis. With the data acquired with the system described in the '208 application and the method for build-to-order described in the co-pending application *Responsive Manufacturing and Inventory Control* (P9153B), the present invention makes it possible to build customized products for implantation. On the one hand, this invention reaches out to where any place products are stored, such as in sales offices, with individual sales representatives, and ultimately at the implanting institution to ensure adequate stock is quickly replaced and always available. These devices include—but are not limited to—implantable pacemakers, cardioverter-

defibrillators, neurological stimulators, leads, drug delivery systems, lead adapters, lead repair kits, etc. On the other hand, this invention may be used to control and manage manufacturing planning and scheduling, forecasting product consumption, purchasing device components, inventory control at the manufacturing facility, vendor management, material tracking, capacity planning, distribution and shipping of finished product, etc.

The required data, for example that a specific device with its associated lead(s), has been implanted may be transferred by the programmer to the Information Network, described in the '976 patent. These data may be downloaded on a real time basis or on a daily basis, usually at night. The Information Network will then summarize these data on a daily basis and issue a build order to replenish the stock that was "consumed" at implant for the specific implanting institution. Specifically, the device type, model number, serial number, name of the implanting physician, the name of the sales representative, the name of the implanting institution are automatically downloaded to the Information Network through the programmer, as substantially described in U.S. Patent No. 5,345,362 and Des. 358,583 by Winkler, both of which are incorporated by reference in their entirety. These data, when received, would in turn automatically initiate a "build-to-order" replenishment to match and replace the device(s) implanted at that institution.

Although the intention of this process is to have a very quick turnaround time, e.g., a total of two days from notification of implant, building the product in an automated assembly line, and delivery of the product, it is also possible that the status of the product build could be made available to all interested parties (purchase agent, physician, sales rep, etc.) on an ongoing basis. Other benefits would include substantial cost savings in manufacturing, reduced product cycle times, reduced obsolescence, reduced inventories at all points in the product delivery chain, and so on. This process will minimize inventory issues for the account, as well as for the manufacturer. In addition it will make it easier to ramp up for the introduction of a new product while, at the same time ramping down the old product. "Phase out" should be much simpler and quicker. With the attainment of these benefits, the costs to the implanting institution can also be controlled and, perhaps, reduced significantly.

Using this invention, the implanting institution's inventory is automatically managed. For example, the Information Network could recommend an alternative device to replace a "used" device. This might occur when products are being phased in or phased out or when a new product is approved for implantation by the specific approving agency in a geographic area. Automatic notifications, based on local regulatory controls, could be placed on labels or within the shipping package so that restrictions on the product's usage, warnings, alerts, etc. could be communicated and implemented. Additionally, the institution and/or implanting physician will be able to monitor the status of the build process, the expected completion, and the status of shipping and scheduled delivery, all of which is commonly known and expected in the shipping industry (i.e., Federal Express or UPS tracking systems).

Additionally, there exists the opportunity to customize the device during the manufacturing process to meet the patient's needs and/or the physician's preferences. For example, the physician could order a specific non-standard lead connector configuration for a specific replacement implant. Specific functions and/or features customized for the patient might be downloaded into the device during the manufacturing process. For example, it is possible to download a patient warning alarm, something similar to a Nokia customized GSM phone ring or, indeed, a voice alert in the patient's own language. Such technology is described in U.S. Pat. Nos. 5,360,437 and 5,891,180 respectively and submitted by reference in their totality. Additionally, specific therapeutic and diagnostic options may be included so as to optimize the device for the patient and his/her specific disease state. An individual physician could specify customized shipping parameters. Such customization might even extend to the shipping labels; they might include the patient's name and identification number, the names of the implanting institution and physician, the scheduled date of implant and/or the location where that implant is to take place (e.g., Operating Room No. 3), as well as the institution's inventory management system label.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an illustration of a body-implantable device system in accordance with the present invention, including a hermetically sealed device implanted in a patient and an external programming unit.

FIG. 2 is a perspective view of the external programming unit of FIG. 1.

FIG. 3 is a block diagram of a system in which the invention is practiced for a patient receiving an implantable medical device, in communication with a Link programmer, which is in communication with the Information Network employing Internet telecommunication and/or satellite linkage.

FIG. 4 is a block diagram of the present invention describing the multiple steps that occur in the manufacturing facility from receipt of the order to shipment of the customized device to the implanting institution.

#### DETAILED DESCRIPTION OF THE DRAWINGS

The present invention uses the Global Communications and Monitoring System (GCMS) described in the '976 patent. This system provides a means for exchanging information with and exercising control over one or more medical devices implanted within the body of a patient employing the patient communications control device. The GCMS is intended to function no matter how geographically remote the patient may be relative to the monitoring site or medical support network. As such, then, during the implant procedure, with the patient in very close proximity to the programmer, there should be no difficulty in establishing communications between the implanted device and the programmer. In this situation, the determines location and details relevant to the device communicates those data via a cellular telephone system link or a satellite based telecommunications link if the patient is outside the range of a cellular link or subscribes only to the satellite-based link.

FIG. 1 is an illustration of an implantable medical device system adapted for use in accordance with the present invention. The medical device system shown in FIG. 1 includes an implantable device 10—a pacemaker for illustration purposes—that has been implanted in a patient 12. In accordance with conventional practice in the art, pacemaker 10 is housed within a hermetically sealed, biologically inert outer casing, which may itself be conductive so as to serve as an indifferent

electrode in the pacemaker's pacing/sensing circuit. One or more pacemaker leads, collectively identified with reference numeral 14 in FIG. 1 are electrically coupled to pacemaker 10 in a conventional manner and extend into the patient's heart 16 via a vein 18. Disposed generally near the distal end of leads 14 are one or more exposed conductive electrodes for receiving electrical cardiac signals and/or for delivering electrical pacing stimuli to heart 16. As will be appreciated by those of ordinary skill in the art, leads 14 may be implanted with their distal end(s) situated in the atrium and/or ventricle of heart 16.

Although the present invention will be described herein in an embodiment which includes a pacemaker, those of ordinary skill in the art having the benefit of the present disclosure will appreciate that the present invention may be advantageously practiced in connection with numerous other types of implantable medical device systems, and indeed in any application in which it is desirable to provide a communication link between two physically separated components.

Also depicted in FIG. 1 is an external programming unit 20 for non-invasive communication with implanted device 10 via uplink and downlink communication channels, to be hereinafter described in further detail. Associated with programming unit 20 is a programming head 22, in accordance with conventional medical device programming systems, for facilitating two-way communication between implanted device 10 and programmer 20. In many known implantable device systems, a programming head such as that depicted in FIG. 1 is positioned on the patient's body over the implant site of the device (usually within 2- to 3-inches of skin contact), such that one or more antennae within the head can send RF signals to, and receive RF signals from, an antenna disposed within the hermetic enclosure of the implanted device or disposed within the connector block of the device, in accordance with common practice in the art. In addition, programmer 20 is also equipped with a transceiver to facilitate communication between programmer 20 and the Internet.

FIG. 2 is a perspective view of programming unit 20 in accordance with the presently disclosed invention. Internally, programmer 20 includes a processing unit (not shown in the Figure) that in accordance with the presently disclosed invention is a personal computer type motherboard, e.g., a computer motherboard including an

Intel Pentium 3 microprocessor and related circuitry such as digital memory. The details of design and operation of the programmer's computer system will not be set forth in detail in the present disclosure, as it is believed that such details are well-known to those of ordinary skill in the art. In addition, there is a transceiver (not shown) that is used to communicate data via landline or wirelessly (telemetry) from the implanted device to an Information Network (see FIGs. 3 and 4).

The FCC has adopted the following definition for describing wireless medical telemetry: "the measurement and recording of physiological parameters and other patient-related information via radiated bi- or unidirectional electromagnetic signals." Thus, in its broadest sense, telemetry can be defined as the art and science of conveying information from one location to another. With radio telemetry, radio signals are utilized to convey that information.

"Telemedicine" is the use of telecommunications and information technology to provide clinical care or data at a distance. The definition of "distance" may range from several yards, such as might occur within a clinic environment or hundreds of miles as occurs in transmission of such data between an implanting institution and an Information Network, as envisaged in the present invention. Wireless technology can be particularly beneficial because developing wireless networks may be faster and cheaper than building a landline infrastructure.

Medical telemetry equipment is increasingly relied upon in hospitals to improve health care and reduce costs. The number of pacemaker patients with chronic medical conditions is rising due to the growth in the elderly population. For these reasons, the need for ensuring the availability of an adequate inventory of pacemakers within the implanting hospital is vital and this need can be fulfilled with medical telemetry equipment such as that used in the programmer depicted in FIG. 2

Referring to FIG. 2, programmer 20 comprises an outer housing 60, which is preferably made of thermal plastic or another suitably rugged yet relatively lightweight material. A carrying handle, designated generally as 62 in FIG. 2, is integrally formed into the front of housing 60. With handle 62, programmer 20 can be carried like a briefcase.

An articulating display screen 64 is disposed on the upper surface of housing 60.

Display screen 64 folds down into a closed position (not shown) when programmer 20 is not in use, thereby reducing the size of programmer 20 and protecting the display surface of display 64 during transportation and storage thereof.

5 A floppy disk drive is disposed within housing 60 and is accessible via a disk insertion slot (not shown). A hard disk drive is also disposed within housing 60, and it is contemplated that a hard disk drive activity indicator, (e.g., an LED, not shown) could be provided to give a visible indication of hard disk activation.

As would be appreciated by those of ordinary skill in the art, it is often desirable to provide a means for determining the status of the patient's conduction system.

10 Normally, programmer 20 is equipped with external ECG leads 24. These leads may be rendered redundant if the implanted device is equipped with a "subcutaneous electrode array" as described in the filed application 09/749,169, *Leadless Fully Automatic Pacemaker Follow-Up*, by Combs, et al, filed December 12, 2000.

15 Programmer 20 is equipped with an internal printer (not shown) so that a hard copy of a patient's ECG or of graphics displayed on the programmer's display screen 64 can be generated. Several types of printers, such as the AR-100 printer available from General Scanning Co., are known and commercially available.

20 In the perspective view of FIG. 2, programmer 20 is shown with articulating display screen 64 having been lifted up into one of a plurality of possible open positions such that the display area thereof is visible to a user situated in front of programmer 20. Articulating display screen is preferably of the LCD or electro-luminescent type, characterized by being relatively thin as compared, for example, a cathode ray tube (CRT) or the like.

25 As would be appreciated by those of ordinary skill in the art, display screen 64 is operatively coupled to the computer circuitry disposed within housing 60 and is adapted to provide a visual display of graphics and/or data under control of the internal computer.

30 Programmer 20 described herein with reference to FIG. 2 is described in more detail in the previously cited U.S. Pat. No. 5,345,362. The Medtronic Model 9790 programmer is the implantable device-programming unit with which the present invention may be advantageously practiced.

FIG. 3 is a block diagram of a system in which the invention is practiced. The major components of the system include patient 12, programmer 20, and Information Network 60. Patient 12 may have multiple implants, for example, an implanted bradycardia type pacemaker 10 with and an implanted ICD 15 that has just been implanted. Confining our attention to ICD 15, we note that this device communicates through RF link 57 to the programmer, specifically to wireless interface 51. Data, such as factory-programmed parameters and so on, are forwarded to system controller 52. Under a physician's direction/prescription, these parameters may be altered and downloaded from system controller 52 to ICD 15 via RF wireless interface 51.

Continuing with FIG. 3 and more to the point of its relation to the present invention, we see that the same data as well as the device's model number, serial number, date of implant, and so on are conveyed to system interface 53. At this juncture, the data may be stored or transmitted/telemetered immediately. The time of transmission is completely dependent on whether the programmer is or is not connected to phone link 56 or satellite link 55 at the time of implant. Assuming that one of these connections is made at some time during the day, the data from Internet interface 53 is uplinked to the Internet via phone line modem connection 56 or telemetric satellite link 55 using data encryption technology for a secure transmission as substantially described in filed application No. 09/431,881, *Method and Apparatus to Secure Data Transfer from Medical Device Systems*, filed November 2, 1999, by Nichols and incorporated herein by reference. Upon reaching Information Network 60, these data are incorporated into the data file containing the complete information relating to the implanting institution, for billing purposes and other uses. These same data are also forwarded to that portion of the network computer related to new build orders for manufacturing, which relates to FIG. 4.

Turning our attention now to FIG. 4, we see the various steps used during the manufacturing process to ensure that the recently implanted ICD (using the example mentioned above) is replaced as quickly as possible. Once the fact that an implant has taken place at a particular institution has occurred and is available in the Information Network 60 (see FIG. 3), that same network, which is constantly monitoring whether a device is to be built as a replacement 70. If not, then the system returns to its



monitoring function 72. If such a replacement is required, then the order to build is downloaded to the manufacturing database 74. At the same time, the database enquires whether there are any common requirements needed to manufacture the product 74. If so, then the database will download all pertinent software relative to the implanted device to the automated manufacturing line. Meanwhile, the database is examined to determine if there are any custom specifications required for this replacement 98. If so, the database retrieves any custom software 100, which will then be downloaded into the device's firmware (ROM) during the building of the device 84. The standard data set will include the device type, model number, serial number, name of the implanting physician, the name of the sales representative, and the name of the implanting institution. The customized data set might include (though not limited to), for example, the following: specific functions and/or features, a patient warning alarm, a voice alert in the patient's own language, customized shipping parameters, shipping labels, patient's name and identification number, name of the implanting institution and physician, scheduled date of implant and/or the location where that implant is to take place (e.g., Operating Room No. 3), as well as the institution's inventory management system label. All these data, when received, will automatically initiate a "build-to-order" replenishment to match and replace the customized device(s) implanted at that institution.

Once the order is made, the manufacturing database will determine whether all components required to complete the build are available 78 at the factory site located nearest to the implanting institution. If components are available, that factory site is selected and scheduled to complete the build 80. If components are not available, the manufacturing database issues an automatic order to the component supplier 94. The required components are noted in the database and an order to the supplier(s) 92 is immediately initiated.

Initiating build 82 with available components or those delivered from the supplier results in building and assembly of the "customized" device, which will replace the implanted device in the inventory of the implanting institution. The implantable device is tested at various steps in the manufacturing process and will

undergo final testing prior to packaging 86. Finally, the device is shipped 88 to the implanting institution 90.

As previously mentioned, the goal for this Responsive Manufacturing and Inventory Control system is to deliver a replacement device within 3 working days of receipt of the information that a device has been implanted and must be replaced.

The preceding specific embodiments are therefore to be understood as illustrative of the many ways in which the principles of the invention may be practiced. It is to be understood, therefore, that other expedients known to those of skill in the art or disclosed herein may be employed without departing from the invention or the scope of the appended claims.

In the following claims, means-plus-function clauses are intended to cover the structures described herein as performing the recited function and not only structural equivalents but also equivalent structures. For example, although a nail and a screw may not be structural equivalents in that a nail employs a cylindrical surface to secure wooden parts together, whereas a screw employs a helical surface, in the environment of fastening wooden parts, a nail and a screw are equivalent structures.

It is therefore to be understood, that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described without actually departing from the spirit and scope of the present invention.